

§ 882.5890

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

§ 882.5900 Preformed craniostomosis strip.

(a) *Identification.* A preformed craniostomosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

§ 882.5910 Dura substitute.

(a) *Identification.* A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

§ 882.5940 Electroconvulsive therapy device.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987]

§ 882.5950 Neurovascular embolization device.

(a) *Identification.* A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. This does not include cyanoacrylates and other embolic

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agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see § 870.3300.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." For availability of this guidance document, see § 882.1(e).

[69 FR 77900, Dec. 29, 2004]

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards).

§ 882.5970 Cranial orthosis.

(a) *Identification.* A cranial orthosis is a device that is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification.* Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

[63 FR 40651, July 30, 1998]

§ 882.5975 Human dura mater.

(a) *Identification.* Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Human Dura

Mater.” See §882.1(e) for the availability of this guidance.

[68 FR 70436, Dec. 18, 2003]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Sec.

884.1 Scope.

884.3 Effective dates of requirement for pre-market approval.

884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Obstetrical and Gynecological Diagnostic Devices

884.1040 Viscometer for cervical mucus.

884.1050 Endocervical aspirator.

884.1060 Endometrial aspirator.

884.1100 Endometrial brush.

884.1175 Endometrial suction curette and accessories.

884.1185 Endometrial washer.

884.1300 Uterotubal carbon dioxide insufflator and accessories.

884.1425 Perineometer.

884.1550 Amniotic fluid sampler (amniocentesis tray).

884.1560 Fetal blood sampler.

884.1600 Transabdominal amnioscope (fetoscope) and accessories.

884.1630 Colposcope.

884.1640 Culdoscope and accessories.

884.1660 Transcervical endoscope (amnioscope) and accessories.

884.1690 Hysteroscope and accessories.

884.1700 Hysteroscopic insufflator.

884.1720 Gynecologic laparoscope and accessories.

884.1730 Laparoscopic insufflator.

Subpart C—Obstetrical and Gynecological Monitoring Devices

884.2050 Obstetric data analyzer.

884.2225 Obstetric-gynecologic ultrasonic imager.

884.2600 Fetal cardiac monitor.

884.2620 Fetal electroencephalographic monitor.

884.2640 Fetal phonocardiographic monitor and accessories.

884.2660 Fetal ultrasonic monitor and accessories.

884.2675 Fetal scalp circular (spiral) electrode and applicator.

884.2685 Fetal scalp clip electrode and applicator.

884.2700 Intrauterine pressure monitor and accessories.

884.2720 External uterine contraction monitor and accessories.

884.2730 Home uterine activity monitor.

884.2740 Perinatal monitoring system and accessories.

884.2800 Computerized labor monitoring system.

884.2900 Fetal stethoscope.

884.2960 Obstetric ultrasonic transducer and accessories.

884.2980 Telethermographic system.

884.2982 Liquid crystal thermographic system.

884.2990 Breast lesion documentation system.

Subpart D—Obstetrical and Gynecological Prosthetic Devices

884.3200 Cervical drain.

884.3575 Vaginal pessary.

884.3650 Fallopian tube prosthesis.

884.3900 Vaginal stent.

Subpart E—Obstetrical and Gynecological Surgical Devices

884.4100 Endoscopic electrocautery and accessories.

884.4120 Gynecologic electrocautery and accessories.

884.4150 Bipolar endoscopic coagulator-cutter and accessories.

884.4160 Unipolar endoscopic coagulator-cutter and accessories.

884.4250 Expandable cervical dilator.

884.4260 Hygroscopic Laminaria cervical dilator.

884.4270 Vibratory cervical dilators.

884.4340 Fetal vacuum extractor.

884.4400 Obstetric forceps.

884.4500 Obstetric fetal destructive instrument.

884.4520 Obstetric-gynecologic general manual instrument.

884.4530 Obstetric-gynecologic specialized manual instrument.

884.4550 Gynecologic surgical laser.

884.4900 Obstetric table and accessories.

Subpart F—Obstetrical and Gynecological Therapeutic Devices

884.5050 Metreurynter-balloon abortion system.

884.5070 Vacuum abortion system.

884.5100 Obstetric anesthesia set.

884.5150 Nonpowered breast pump.

884.5160 Powered breast pump.

884.5225 Abdominal decompression chamber.

884.5250 Cervical cap.

884.5300 Condom.

884.5310 Condom with spermicidal lubricant.

884.5320 Glans sheath.

884.5330 Female condom.

884.5350 Contraceptive diaphragm and accessories.

884.5360 Contraceptive intrauterine device (IUD) and introducer.